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§ 381.461 Nutrient content claims for the sodium content.

- (a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:
- (1) The claim uses one of the terms defined in this section in accordance with the definition for that term;
- (2) The claim is made in accordance with the general requirements for nutrient content claims in §381.413; and
- (3) The product for which the claim is made is labeled in accordance with § 381.409.
- (b) Sodium content claims. (1) The terms "sodium free," "free of sodium," "no sodium," "zero sodium," "without sodium," "trivial source of sodium," "negligible source of sodium," or "dietarily insignificant source of sodium" may be used on the label or in labeling of products, provided that:
- (i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 5 mg of sodium per labeled serving size;
- (ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of sodium," "adds a negligible amount of sodium" or "adds a dietarily insignificant amount of sodium;" and
- (iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (2) The terms "very low sodium" or "very low in sodium" may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l), provided that:
- (i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

- (B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form); and
- (ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:
- (i) The product contains 35 mg or less of sodium per 100 g of product; and
- (ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (4) The terms "low sodium," "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in labeling of products, except meal-type products as defined in §381.413(l), provided that:
- (i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or
- (B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients

per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form); and

- (ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

- (ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (6) The terms "reduced sodium," "reduced in sodium," "sodium reduced," "less sodium," "lower sodium," or "lower in sodium" may be used on the label or in labeling of products, except meal-type products as defined in §381.413(1), provided that:
- (i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in §381.413(j)(l); and
- (ii) As required in §381.413(j)(2) for relative claims:
- (A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium product, 50 percent less sodium than regular product"); and
- (B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been lowered from 300 to 150 mg per serving").
- (iii) Claims described in paragraph (b)(6) of this section may not be made

- on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low sodium."
- (7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:
- (i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in §381.413(j)(l); and
- (ii) As required in §381.413(j)(2) for relative claims:
- (A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product"—30% less sodium per 3 oz than our 'regular product'"); and
- (B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz").
- (iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for "low sodium."
- (c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted," "no salt," "no salt added" are potentially misleading.
- (1) The term "salt free" may be used on the label or in labeling of products only if the product is "sodium free" as defined in paragraph (b)(1) of this section.
- (2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of products only if:
 - (i) No salt is added during processing;
- (ii) The product that it resembles and for which it substitutes is normally processed with salt; and

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- (iii) If the product is not sodium free, the statement "not a sodium free product" or "not for control of sodium in the diet" appears adjacent to the nutrition information of the product bearing the claim.
- (3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 213, Jan. 3, 1995; 60 FR 5762, Jan. 30, 1995]

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content

- (a) General requirements. A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:
- (1) The claim uses one of the terms defined in this section in accordance with the definition for that term;
- (2) The claim is made in accordance with the general requirements for nutrient content claims in §381.413; and
- (3) The product for which the claim is made is labeled in accordance with § 381.409.
- (b) Fat content claims. (1) The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of products, provided that:
- (i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a mealtype product, less than 0.5 g of fat per labeled serving size;
- (ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat"; and

- (iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.
- (2) The terms "low fat," "low in fat," "contains a small amount of fat," "low source of fat," or "little fat" may be used on the label and in labeling of products, except meal-type products as defined in §381.413(l), provided that:
- (i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or
- (B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in \$381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).
- (ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches
- (3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:
- (i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat: and
- (ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.